K051978
Page 1 of 2

SEP 23 2005

510(k) SUMMARY
Trabecular Metal Vertebral Body Replacement System

Submitter Name And Address:	Zimmer Trabecular Metal Technology, Inc. 80 Commerce Drive Allendale, New Jersey 07401-1600
Contact Person:	Marci Halevi
Phone Number:	(201) 818-1800 ext. 507
Fax Number:	(973) 829-0825
Date Prepared:	July 11, 2005
Device Trade Name:	Trabecular Metal Vertebral Body Replacement System
Device Common Name:	Vertebral Body Replacement Device
Classification Number and Name:	21 CFR § 888.3060 Spinal Intervertebral Body Fixation Orthrosis

---

Device Description:

The Trabecular Metal Vertebral Body Replacement System is designed to be used as a replacement for a single diseased or damaged vertebral body and the adjacent disc when spinal surgery through an anterior approach is indicated.

The Trabecular Metal Vertebral Body Replacement (VBR) System is comprised wholly of Trabecular Metal Porous Tantalum. The VBR is available to accommodate replacement of a vertebral body in the thoracic and lumbar region of the spine. The device is available in a variety of cross sections and heights to properly tension the spine.

The superior and inferior surfaces of the device have a pattern of ripples to provide increased stability.

Indications for Use:

The Zimmer TMT Trabecular Metal Vertebral Body Replacement System is comprised of vertebral body replacement devices intended for use in the thoracolumbar spine (T1 – L5) to replace a collapsed, damaged or unstable vertebral body due to tumor or trauma (i.e., fracture). The Trabecular Metal Vertebral Body Replacement is intended for use with supplemental internal spinal fixation systems. The Trabecular Metal Vertebral Body Replacement may be used with bone graft.

Device Technological Characteristics and Comparison to Predicate Device:

The device is unique in comparison to predicates for this indication with regard to its geometry. The material has been used in cited predicates for other applications. The Zimmer TMT Vertebral Body Replacement System is substantially equivalent to previously cleared components of this same system (K010378, K021025, K021967, K022563, K031823, K032527 and K051196). The size range is comparable to the Signus

Medical implants described in K022793, K041888 and K043316.

Performance Data: Predicate devices that are a part of the Trabecular Metal Vertebral Body Replacement System were tested per applicable standards (reference K010378). Biocompatibility data was provided to support the material's use. Performance testing was provided to support equivalent mechanical behavior to the predicate devices. The results demonstrated that the device will perform as intended and is equivalent to the cited predicate devices. Test data was provided regarding:

- Static compression,
- Dynamic compression,
- Static torsion,
- Dynamic torsion, and
- Abrasion.

Conclusion: The Zimmer TMT Trabecular Metal Vertebral Body Replacement System is substantially equivalent to the predicate devices identified in this premarket notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 3 2005

Ms. Marci Halevi
Manager of Regulatory Affairs
Zimmer Trabecular Metal Technology, Inc.
80 Commerce Drive
Allendale, New Jersey 07401-1600

Re: K051978
Trade/Device Name: Zimmer Trabecular Metal Vertebral Body Replacement System
Regulation Name: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: MQP
Dated: July 20, 2005
Received: July 21, 2005

Dear Ms. Halevi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051978

Device Name: The Zimmer TMT Trabecular Metal Vertebral Body Replacement System

Indications for Use:

The Trabecular Metal Vertebral Body Replacement System is a vertebral body replacement device intended for use in the thoracolumbar spine (T1 – L5) to replace a collapsed, damaged or unstable vertebral body due to tumor or trauma (i.e., fracture). The Trabecular Metal Vertebral Body Replacement is intended for use with supplemental internal spinal fixation systems. The Trabecular Metal Vertebral Body Replacement may be used with bone graft.

The Zimmer TMT Trabecular Metal Vertebral Body Replacement System

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K051978

(Posted November 13, 2003)